Press Release

Parliament compromise on pharmaceutical legislation accelerates much needed reform

Brussels, 19 March 2024

Today, the Members of the Parliament's health committee (ENVI) adopted a compromise position on the EU Pharmaceutical legislation review (comprising of a new Pharmaceutical Directive and Regulation). The Parliament has prioritised advancing this important legislation to improve the access, availability, and affordability of medicines ahead of the EU elections in June 2024 and prevent further delays of this much needed reform.

Medicines for Europe recognises the hard work of the rapporteurs and of so many highly engaged individual members, as political groups had to move their positions significantly to find a compromise on such a substantial and very complex legislation in near record time.

While imperfect, the compromise includes many improvements:

1. Regulatory data protection will be extended but will remain closer to the current level of protection. It continues to provide by far the longest protection period in the world. In exchange for this extension, we would like to see more effort to ensure equitable access across the Union.
2. The harmonised Bolar provision has been clarified in line with the intention of the proposal to encourage more development in Europe (API production) and to prevent access delays to generic and biosimilar medicines at SPC expiry. Generic and biosimilar medicines will however continue to be delayed in tender procedures, which are still not included in the revised Bolar.
3. The costly AMR voucher will be a last resort tool to stimulate research and development of antimicrobials but will still not deliver on the objectives of the proposals. On the contrary, an EU guaranteed reserve will fulfil these objectives.
4. The legislation supports affordable innovation through specific measures for medicines repurposing although its most complex forms, including reformulations, should be clarified in the text.
5. The regulatory efficiency and digitalisation measures, including the need to facilitate the availability of off-patent medicines, remains a core element of the legislation. These reforms should be fast-tracked to ensure more medicines availability.
6. There are some improvements to the shortages and environmental aspects of the legislation. However, there is still a lot of progress needed to develop a true shortage prevention policy and to maintain a coherent risk/benefit policy for medicines authorisations.

Looking forward, Medicines for Europe will engage constructively with the Council to further improve the of the pharmaceutical legislation to deliver more access, wider availability and to secure the supply of affordable medicines for European patients.

Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality,

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value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D investment. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information, please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU.